REMARKS/ARGUMENTS

The claims are 1, 3-16, 18-20 and 22-25. Claims 1 and 25 have been amended to better define the invention and to incorporate subject matter previously appearing in claim 2. Accordingly, claim 2 has been canceled. In addition, claim 16 has been amended to better define the invention and to incorporate subject matter previously appearing in claim 17. Accordingly, claim 17 has been canceled. Claims 3, 5-13 and 15 have also been amended to better define the invention. Support for the claims may be found, *inter alia*, in the disclosure at pages 11-14, 16, 17 and 20, and FIGS. 1 and 3-5. Reconsideration is expressly requested.

Claims 1-20 and 22-25 were rejected under 35 U.S.C. 102(b) as being anticipated by *Neracher WO 02/49697*. Claims 1, 13-14 and 17-18 were rejected under 35 U.S.C. 102(b) as being anticipated by *Dixon U.S. Patent No. 4,722,728*.

In response, Applicant has, *inter alia*, amended claim 1 to incorporate the subject matter of claim 2, thereby obviating the rejection of claim 1 and dependent claims 13-14 and 17-18 on the basis of the *Dixon*. The Examiner's rejection of the claims on

the basis of *Neracher* is respectfully traversed for the following reasons.

As set forth in claim 1 as amended, Applicant's invention provides a device for needle-free injection of a medium into the tissue of a human or an animal, including a needle-free pre-injection device and a main injection device. The pre-injection device includes a first chamber accommodating a pre-injection medium for production of a high-pressure jet of the pre-injection medium for producing an injection channel by means of a high pressure and a small volume. The main injection device includes a second chamber accommodating a medium to be injected, the medium being injected with a great volume and a low pressure in comparison with the volume and pressure of the pre-injection device.

A nozzle intended to be set onto the skin is connected with the chamber of the pre-injection device and with the outlet of the main injection device by way of a kick-back valve. A pressure-production device that is connected with the chamber of the pre-injection device is configured to produce a high-pressure jet from the nozzle that penetrates the tissue. The chamber of the pre-injection device has a volume sized exclusively for

producing an injection channel in the tissue, and the chamber of the main injection device has a volume intended for the medium to be injected.

As set forth in claim 4, Applicant's invention provides a device for needle-free production of an injection channel in the tissue of a human or an animal, for introduction of a medium to be injected into the tissue, wherein a pre-injection device is provided ahead of a main injection device that contains the medium to be injected, and a chamber of the pre-injection device provided for accommodation of a pre-injection medium has a nozzle intended to be set onto the skin. The pre-injection device has a pressure-production device for producing a high-pressure jet of the pre-injection medium that exits from the nozzle, and the chamber has a volume sized exclusively for producing the injection channel.

As set forth in claim 25 as amended, Applicant's invention provides a method for needle-free injection of a medium into human or animal tissue including the steps of providing a device comprising a needle-free pre-injection device and a main injection device. The pre-injection device includes a first

chamber accommodating a pre-injection medium for production of a high pressure jet of the pre-injection medium for producing injection channel with a high pressure and a small volume. The main injection device includes a second chamber accommodating a medium to be injected, the medium being injected with a great volume and a low pressure in comparison with the volume and pressure of the pre-injection device.

In accordance with the method, the high-pressure jet of the pre-injection medium is first produced via the needle-free pre-injection device, the injection channel is produced with the high-pressure jet, and the medium to be injected is subsequently introduced into the tissue of the injection channel. A nozzle intended to be set onto the skin is connected with the chamber of the pre-injection device and with the outlet of the main injection device by way of a kick-back valve, and a pressure-production device that is connected with the chamber of the pre-injection device is configured to produce a high-pressure jet from the nozzle that penetrates the tissue. The chamber of the pre-injection device has a volume sized exclusively for producing an injection channel in the tissue, and the chamber of the main injection device has a volume intended for the medium to be injected.

By means of the configuration set forth in Applicant's claim 1 as amended, claim 4, and claim 25 as amended, an injection channel is first produced using a pre-injection device by means of a high pressure jet. In contrast to prior devices, however, the amount to be introduced into the tissue for the production of the high-pressured jet can be kept particularly low. With this arrangement, it is not necessary to bring the entire amount of the medium to be injected into the tissue as a high-pressure jet. Rather only a very slight amount is required for the production of high-pressured jet. As a result, the tissue is handled gently, which results in the ability to introduce a large amount of the medium to be injected into the tissue by means of the injection channel by the high-pressured jet, and distribute it in the tissue.

As the Examiner has recognized the compressible substance 7 of *Neracher* acts like a spring; however, the Examiner takes the position that *Neracher* discloses a main injection device, which it is respectfully submitted is incorrect. A main injection device contains an injectable medium and according to the Examiner's position, *Neracher* would inject the compressible substance 7 (which *Neracher* describes at page 3, lines 28 - 29 as polysiloxane, oils or gels or vulcanized silicon rubber) into the

patient as the volume of the main injection device. See page 3, lines 2 - 3 of the Office Action. It is respectfully submitted that the Examiner's position is incorrect and results from a misunderstanding of the *Neracher* device.

Although the Examiner has taken the position that intended use cannot differentiate the claimed apparatus from the prior art if the prior art is capable of performing the intended use, it is respectfully submitted that the *Neracher* device is not capable of performing the intended use as recited in Applicant's claims 1, 4 and 25. Moreover, it is respectfully submitted that the structure set forth in claims 1, 4 and 25 sufficiently differentiates Applicant's device and method from the device of *Neracher*. It is respectfully submitted that the device in *Neracher* is not capable of injecting a pre and a main injection volume. Rather, the device of *Neracher* injects one volume from a single injection chamber with two different pressures which is shown in FIG. 2f of *Neracher*, whereas with Applicant's device and method two different media are injected with different pressures.

The Examiner has also taken the position that a valve is disclosed by *Neracher* and in fact two kinds of valves are disclosed by *Neracher*. The first one is the valves 14 and 15 cited by the Examiner at page 3, line 11 of the Office Action.

These valves are part of the activation-regeneration cycle of the propulsive system using the compressible substance 7. It is respectfully submitted that these valves are not part of the injection process itself and are not passed by the medium to be injected.

The second kind of valves disclosed by *Neracher* is used to block the nozzle orifice (see page 5, line 16 of *Neracher*). If a kick-back valve as recited in Applicant's claims is used at this position, no injection is possible any more. Applicant's invention as recited in claims 1, 4 and 25 do not relate to the use of kick-back valves in general, but rather to the special use of a kick-back valve between the pre-injection and the main-injection chamber. As shown in FIG. 1 and at page 12, lines 2 and 3 of Applicant's disclosure, the kick-back valve 5 is located below the connection 3 connecting the pre-injection chamber 4 and the channel 8. The kick-back valve as recited in Applicant's claims 1, 4 and 25 is needed to shut the main-injection device during pre-injection. The kick-back valve is closed automatically if the pre-injection chamber is filled with the pre-injection medium. After pre-injection the valve opens automatically by the difference of pressures and the main injection begins. It is respectfully submitted that this arrangement is not shown by *Neracher*.

Although the Examiner has taken the position that reference numbers 237 (housing), 16 (the actuation button) and 239 (flange) of *Neracher* are coupling devices, it is respectfully submitted that the Examiner's position is incorrect. The term "coupling" requires at least two different parts which are to be combined. As the device of *Neracher* is a single part device no coupling is needed.

Although the Examiner has divided the device of *Neracher* into two parts, it is respectfully submitted that there is no reason to do so. If the container 4 were divided into two parts a gap should be shown in the wall shown in FIG. 1. It is respectfully submitted, moreover, that the dotted line is set arbitrarily to define the chamber 12 as belonging to the "main injection device" and chamber 13 as belonging to the "pre-injection device". Both chambers are connected via the valves 14 and 15 and belong to the propulsion system. The compressible substance is located in chamber 12 before injection and in chamber 13 after the injection. Accordingly, it is respectfully submitted that there is no reason to associate the actuation mechanism to the "pre-injection device" and not to the "main injection device" as suggested by the Examiner. In any event, the terms "pre-injection device" and "main injection device" as recited in Applicant's claims 1, 4 and 25 require the existence

of two different volumes of media which are injected, whereas only one volume 2 in capsule 3 is disclosed in *Neracher*.

Claim 3, as amended, further specifies that the chamber of the main injection device accommodating a predetermined amount of the medium to be injected has a piston that can be moved by hand. The piston 9 of *Neracher* is moved before the injection in order to tense the propulsive system. See page 12, lines 23-27 of *Neracher*. Further chamber 7 does not contain the medium to be injected, but rather the compressable substance as discussed above. In contrast, as recited in Applicant's claim 3 as amended, the piston 18 is moved by hand during the injection and is used for starting the actuation system for pre-injection (see Applicant's disclosure at page 16 and FIG. 3) and for injecting the main injection volume (see Applicant's disclosure at page 17 and FIG. 5. Thus, in contrast to *Neracher*, the piston of Applicant's device as recited in claim 3 as amended is in direct contact with the medium to be injected.

Claim 5 is dependent on claim 4, and further specifies that the pre-injection device has a coupling device for a connection with the main injection device that contains the medium to be injected. If the "housing portion" 237 of *Neracher* is a coupling device as stated by the Examiner, the main volume of medium which

is injected would be the compressible substance 7. The disconnection between the injection volume 2 and the propulsive force 7 can be seen clearly in FIG. 2a of *Neracher*. The Examiner himself has recognized that a spring (245/246) can be located between the compressible substance 7 and the piston 210 (see page 4, line 2 of the Office Action) which pushes the injectable medium 2 through the nozzle at *Neracher*. Thus, it is respectfully submitted that claim 5 is patentable over *Neracher* for this additional reason.

Claim 6 is dependent on claim 1 and specifies that the pressure-producing device of the pre-injection device has a movable pressure plate biased by a spring force, or a biased pressure piece, wherein the movable pressure plate is pressed into the pre-injection device. The pressure plate 7 is movable into the chamber 4 of the pre-injection device (see page 4, lines 5-8 and FIGS. 3 and 4 of Applicant's disclosure) and located between the piston 6 and a pressure-production device 14. (See page 12, line 20 to page 13, line 4 of Applicant's disclosure.) Plate 11 of *Neracher* is non-moveable and is located inside the pressure-production device. Reference numbers 234 (a moveable stop pin) and 239 (a flange) (see *Neracher* page 13, lines 29-31) belong to the pressure retaining means 206 of *Neracher*. Thus,

they are located outside the injection device and cannot be moved into the chamber 2 as recited in Applicant's claim 6.

Claim 7 specifies that the pre-injection device has a channel connected with the nozzle at one end and the chamber of the main injection device containing the injectable medium at the other end. Although the Examiner has taken the position that channel 205 of *Neracher* is connected to the nozzle, as shown in FIG. 1 of Applicant's disclosure and as recited in claim 8, the channel 8 is connected to the nozzle at one end and to the main injection device at the other end. More specifically, channel 8 is connected to the chamber 19 of the main injection device, which contains the injectable medium. See page 11, line 18 to page 12, line 10 and FIG. 1 of Applicant's disclosure.

Contrary to the Examiner's position, moreover, element 17 of FIG. 1 and element 205 FIG. 2 of *Neracher* are not connected with the nozzle. The capsule containing the injectable liquid 2 is connected with the environment only at one end via the nozzle 20. At the other end the capsule piston 19 closes the capsule. There is no connection to the environment via the capsule piston 19 of *Neracher*. If such a connection would exist an injection would not be possible because the liquid would not be pressed through the nozzle, but rather through the capsule piston. Element 3 of

FIG. 2 is the capsule itself. Thus, element 3 is connected with the nozzle, but not with a chamber of the main injection device at the other end of the channel.

Claim 8 specifies that a kick-back valve is disposed within the channel below the connection to the chamber of the pre-injection device. As discussed previously, this arrangement neither disclosed nor suggested by *Neracher*.

Claim 9 specifies that a trigger of the pre-injection device holds a movable pressure plate biased by a spring or a pressure piece in its base position. Claim 10 specifies that the trigger is connected with the chamber of the pre-injection device and is configured to release the movable pressure plate above a planned pressure. It is respectfully submitted that a movable pressure plate is nowhere disclosed or suggested by *Neracher*. In addition, it is respectfully submitted that a spring or any means acting like a spring is not seen in FIG. 1 of *Neracher* and is unnecessary to fix the button 16 at its position, because the propulsive force of *Neracher*'s device is directed perpendicular to the button 16. Pressing of the button 16 opens the valve 15 and lets the compressible substance flow into the front chamber 13.

Claim 11 specifies that a membrane is part of the piston, with which the chamber of the injection medium is connected, and this membrane is deflected in the direction of a pusher to activate the trigger by way of the pusher. In *Neracher*, the capsule piston 19 may be provided with a cone shaped elastic member 21 (see page 12, lines 18 - 20 of *Neracher*). After actuation of the device (by pressing the button 16, see page 12, line 31 of *Neracher*) the piston 19 is driven by the propulsion system piston 10. The actuation system using the abutment shoulder 235, as discussed in Applicant's previous Amendment, likewise uses a direct actuation system. In both systems the elastic member 21 is moved after actuation. In contrast, in Applicant's device as recited in claim 11 as amended, the deflection of the membrane is used to activate the pusher. See page 14, lines 1-7 of Applicant's disclosure.

Claim 12 specifies that the channel has a connection with the chamber of the pre-injection medium, wherein the kick-back valve is disposed between the connection and the coupling device. See page 12, lines 2 and 3 and FIG. 1 of Applicant's disclosure. It is respectfully submitted that this arrangement is nowhere disclosed or suggested by *Neracher*.

As recited in claim 13 as amended, the chamber has a piston that rests against the movable pressure plate and can be displaced in length, and the channel is guided through the piston and the movable pressure plate. Thus, Applicant's pressure plate is movable into the chamber 4 of the pre-injection device in contrast to plate 11 of *Neracher*. Further, no channel is guided through the pistons by *Neracher*.

Claim 14 specifies that the main injection device and the pre-injection device have a common nozzle. As the compressible substance 7 is not injected by *Neracher* no common nozzle exists. As discussed above, it is respectfully submitted that the compressible substance 7 of *Neracher* is not injected, and the actuation mechanisms used by *Neracher* are different from those used by Applicant.

Claim 15 specifies that a trigger of the pre-injection device can be indirectly activated by the pressure produced by the main injection device deflecting the membrane in the direction of a pusher. The system of *Neracher* is actuated directly by pressing the button 16 (see page 12, line 10 of *Neracher*) or the actuation lever 240 (see page 13, line 29 of page 14, line 2 of *Neracher*). In contrast the deflection of the membrane caused by the increasing pressure in the chamber 4 is

used to activate the pusher (see page 14, lines 1-7 of Applicant's disclosure). The injection is actuated without a direct action of the user. Only the correct contact pressure is needed to start the injection automatically. Thus, it is respectfully submitted that claim 15 is patentable over *Neracher* for this additional reason.

Claim 16 further specifies that the pre-injection device and the main injection device have a common chamber for accommodating the medium to be injected, and a common pressure-production device, wherein the pressure-production device has means for reducing the size of a first, slight part of the chamber in a first step, by a small volume, at a great pressure, and, in a second step, by a great volume, at a low pressure, and wherein the common pressure-production device has a single spring and damping means for damping the movement of a piston that delimits the common chamber, the damping means including a piston rod having a damping disk that stands opposite a fixed damping track. Reference number 5 of *Neracher* refers to a pressure transmitting member in the form of a piston 10 (see *Neracher*, page 9, lines 14 - 15). The pressure retaining means 206 is disclosed at page 13, line 16 to page 14, line 4 of *Neracher*. Further, chamber 4 and 204 of *Neracher* do <u>not</u> contain the medium to be injected, but the compressable substance 7. Thus, it is respectfully submitted

that claim 16 is patentable over *Neracher* for this additional reason.

Claim 18 further specifies that the common pressure-production device has two springs having different spring stiffness values and spring paths, whereby a first spring element for moving the piston in the first step has a high spring stiffness and a short spring path, and the second spring for moving the piston has a low spring stiffness and a long spring path. In contrast, *Neracher* fails to disclose or suggest two springs but rather a compressible substance acting like a spring (FIG. 1) and in addition one spring (FIG 2). Thus, it is respectfully submitted that claim 18 is patentable over *Neracher* for this additional reason.

Accordingly it is respectfully submitted that Applicant's device as recited in claims 1 and 4 and in new claim 25 are patentable over the cited references together with the dependent claims, which depend directly or indirectly on one of these claims.

In summary, claims 1, 3, 5-13, 15-16 and 25 have been amended, and claims 2 and 17 have been canceled. In view of the

foregoing, withdrawal of the final action and allowance of this application are respectfully requested.

Respectfully submitted,
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